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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/101,283 01/18/98 FISHER S 02307E-06001

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EXAMINER

HOUTTEMAN, S

ART UNIT

PAPER NUMBER

1656

10

DATE MAILED:

01/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/101,283

Applicant(s)
Fisher et al.

Examiner
Scott Houtteman

Group Art Unit
1656



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) 3, 4, and 22 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, and 5-21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 3, 4 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species. Election of the species "Protein A" was made in response to a phone call on December 15, 2000.

2. Claims 5-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-22 recite methods of culturing human fetal trophoblast cells. These claims are indefinite in several aspects.

The purpose of the method is unclear. Claim 5 seems to be a method of growing a cell type. Claim 5 is not limited to any particular protein. In contrast, other dependent claims, such as claim 6 recite measuring the release of protein A. Thus, claim 6 appears to be some sort of diagnostic method. However, it is unclear what is being diagnosed, the presence of a disease or merely the health of the cultured cells.

The claims recite measuring "release." It is unclear what property is referred to as "release." It is not clear if this means release of the protein from the nucleus, from the cell into an extracellular space or release of binding of the protein to a ligand. The characteristic to be measured is also unclear; protein concentration, amount of protein in a particular subcellular region, conformation of the protein are all possibilities.

Other claims are vague in the recitation of purposes such as "abnormal placental function," for example "preeclampsia," "invasiveness" of trophoblasts, determining if proteins are present in

“metastatic cells.” The claims, however, are silent on just how one carries out these complex purposes. It is unclear whether some complex statistical study is required that yields results relevant only to populations of patients, or if some specific result is indicative of the present of these conditions in a single patient. If the latter is the case the claims are unclear on what specific end product is to be measured and what that end product indicates.

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 5-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not disclosed in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention.

The claims of this case are extremely broad. Claims 5-21 are broadly drawn to a myriad of uses for protein A. (Note, however, that Claim 5, drawn only to a method of culturing human fetal trophoblast cells in less than about 20% oxygen atmosphere, is not even limited to the use of any single protein.) Claims 6-22 further limit claim 5 to recite measuring the release of protein A. However, these claims read on any use of the protein to diagnose or screen for any disease. Only claims 12-14 and 19 recite specific conditions, but these claims are broadly drawn to any and all steps by which one can identify these conditions.

The specification offers little guidance in enabling a reasonable number of embodiments of these broad claims. The specification merely discloses that then certain cell types are grown in oxygen starved (hypoxic) conditions, certain proteins will have altered steady state levels. The specification does not disclose how these levels can be correlated to the diagnosis of any disease or condition.

The specification discloses that this is a highly unpredictable field. For example, the specification discloses that it is desirable to detect the presence of certain conditions, such as spontaneous abortion. The specification, conceded, however, on pages 2-3 that "Despite decades of interest and research, the pathogenesis of this disease is still poorly understood" and "Despite the recent focus on molecular events underlying preeclampsia, relatively little is known regarding the etiology of this and related diseases of pregnancy."

The specification discloses that a decrease in one specific protein "pregnancy-specific beta-1-glycoprotein" could be associated with fetal malnutrition. The specification, however does not show any nexus between this protein and protein A, the subject of the current claims.

The specification fails to show some nexus exists between measurements of protein A and any practical use. The specification merely make the case that protein A is an interesting subject of further study. Accordingly, the skilled artisan would be forced to undergo the undue experimentation of carrying out this further study and determining whether protein A can be correlated with any disease or condition and developing specific methods by which this correlation can be measured.

4. Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the

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Art Unit 1656

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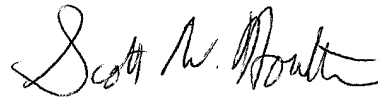
Official Gazette, 1096 OG 30 (November 15, 1989). The Technology Center 1600 Fax numbers are (703) 305-3014 and 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 5:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman
December 4, 2000



**SCOTT W. HOUTTEMAN
PRIMARY EXAMINER**